K093806 (1/3)

APR - 8 2010

Medacta International

**510(k) Summary**


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Date Prepared: April 7, 2010

DEVICE INFORMATION

Trade/Proprietary Name: MyKnee Cutting Blocks

Common Name: Total Joint Replacement
/Classification Name: Knee Joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

21 CFR 888.3560
Class II
Device Product Code: JWH, OOG

Predicate Devices: K082358 Smith & Nephew, Inc. Patient Matched Cutting Blocks
K090988 GMK Total Knee System

Product Description:
MyKnee Cutting Blocks are designed and manufactured from patient imaging data so that the cutting blocks match the patient's anatomy. The MyKnee Cutting blocks for the patient are used with Medacta's existing GMK Total Knee System.

Intended Use and Indications for Use:
MyKnee Cutting Blocks are intended to be used as anatomical cutting blocks specific for a single patient anatomy to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting.

MyKnee Cutting Blocks are intended for use with GMK Total Knee System and its cleared indications for use.

MyKnee Cutting Blocks are intended for single use only.

Comparison to Predicate Devices
MyKnee Cutting Blocks have the same intended use as the Smith & Nephew's Patient Matched Cutting Blocks except for use with the Medacta GMK system instead of the Smith & Nephew's cleared total knee systems. Both are manufactured from the same material using the type of process where the cutting blocks are matched to the patient's anatomy using data from patient imaging files.

MyKnee Cutting Blocks are also substantially equivalent to the standard distal femoral and proximal tibial cutting blocks used in conjunction with the GMK Total Knee system cleared under K090988. MyKnee Cutting Blocks are used with the GMK Total Knee System for the indications for use for which the GMK Total Knee System is cleared.

Performance Testing
No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the MyKnee Cutting Blocks was conducted in accordance with various international standards and FDA guidance documents.

Non-clinical testing included biocompatibility testing to ISO 10993 applicable to external communicating devices with limited (<=24 hrs) contact duration, dimensional accuracy and precision before and after sterilization, mechanical testing, cleanliness following factory cleaning, and a shipping test of the packaged device. Process reproducibility was assessed. The software tools used to manufacture the MyKnee Cutting Blocks were validated for their intended use.

MyKnee Cutting Blocks were tested as part of design verification to written protocols with pre-defined acceptance criteria. The testing was conducted on the worst case component size and option/design. The testing met all acceptance criteria and verifies that the performance of the MyKnee Cutting Blocks are substantially equivalent to the predicate devices.

Design validation was accomplished with a cadaver laboratory.

Conclusion:
The data and information provided in this submission support the conclusion that the MyKnee Cutting Blocks are substantially equivalent to its predicate devices, the Smith & Nephew, Inc. Patient Matched Cutting Blocks and/or the GMK Total Knee System with respect to intended use, design, materials, and operational principles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medacta International
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APR - 8 2010

Re: K093806
Trade/Device Name: MyKnee Cutting Blocks
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH, OOG
Dated: April 2, 2010
Received: April 5, 2010

Dear Ms. Kennel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K093806

Device Name: MyKnee Cutting Blocks

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices



510(k) Number K093806